MAY 1 9 2000

510(k) Summary

K000133

Applicant's Name and Address: Menicon Co., Ltd.
21-19, Aoi 3-Chome
Naka-ku, Nagoya 460-0006
Japan
Phone 011 81 52 935 1676
Fax 011 81 52 935 1633

Contact Person: Alex Kato
Menicon U.S.A. Inc.
333 West Pontiac Way
Clovis, CA 93612
Phone (209) 292-2020
Fax (209) 292-2021

Summary Prepared May 2000

Trade Name:

Menicon Z™ (tisilfocon A) Rigid Gas Permeable Contact Lens

Device Generic Name:

tisilfocon A

Classification Name:

Lens, contact (other material) – daily wear

Common/Usual Name

Rigid gas permeable contact lens

Predicate Device:

Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens

Device Description:

The lens material (tisilfocon A) is a thermoset copolymer derived from fluoro-methacrylate and siloxanylstyrene, bound by crosslinking agents. The lens is available in light blue and violet tints. The blue lens is tinted with color additive D & C Green No. 6 and the violet lens contains the color additives D & C Green No. 6 and D & C Violet No. 2. Also, UV absorber is added (Tinuvin 326).

Solution used for wet-storage packaging of Menicon Z lenses:

BARNES-HIND® ComfortCare® GP WETTING & SOAKING SOLUTION, which contains edetate disodium and chlorhexidine gluconate as preservatives.

Indications for Use:

Menicon Z (tisilfocon A) spherical lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

Menicon Z (tisilfocon A) toric and multifocal lenses are indicated for daily wear for the correction of refractive error (myopia, hyperopia, presbyopia and/or astigmatism) in aphakic and non-aphakic persons with non-diseased eyes.

The lens may be disinfected using a chemical disinfection system only.

Substantial Equivalence:

Menicon Z RGP lenses manufactured at additional finishing laboratories are substantially equivalent to the Menicon Z RGP lenses manufactured at Menicon USA, Inc.

No testing was performed in support of this application which is submitted in accordance with the May 1994 Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses, "Procedure for Adding Lens Finishing Laboratories for Manufacturing and Marketing of Class II Rigid Gas Permeable Contact Lenses."

The safety and efficacy of the Menicon Z lenses was demonstrated in the following previously cleared applications: K962006, K970019 and K972443.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Menicon U.S.A., Inc.
c/o Beverley Venuti, Ph.D., R.A.C.
Staff Consultant
Foresight Regulatory Strategies, Inc.
269 A Ballardvale Street
Wilmington, MA 01887

Re: K000133
Trade Name: Menicon Z ™ (tisilfocon A) Rigid Gas Permeable Contact Lens for Daily Wear
(protocol for adding lens finishing laboratories)
Regulatory Class: II
Product Code: 86 HQD
Dated: April 11, 2000
Received: April 13, 2000

Dear Dr. Venuti:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Menicon Z™ Rigid Gas Permeable Contact Lens

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000133

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 80.109)

(Optional Format 1-2-96)